

REMARKS:

The Examiner's Office Action has been reviewed and considered, and revised claims are submitted in light of the Examiner's comments. Applicant apologizes for the incorrect claim-numbering in the prior amendments. The listing of claims is believed to be accurate and in accordance with the Examiner's corrected numbering of the claims.

With regard to the abstract, a separate sheet is attached with a replacement abstract that meets the length requirements of the rules. This is the same proposed abstract that was submitted with the Amendment dated November 24, 2003.

With regard to the rejection of claim 1 (and dependent claims 62, 64 and 66) under 35 U.S.C. §112, the portions that the Examiner considered to be new and indefinite matter have been removed from claim 1. This amendment is believed to remove the basis for the 112 rejections.

The subject matter of claim 2 has been added to claim 1. This is believe to remove the basis for rejecting claims 1, 62 and 66 under Section 102.

Obviousness

The following comments address the four references the examiner relied upon in raising a case of *prima facie* obviousness.

The examiner is requested to reconsider the applicability of Levin et al. which teaches that policosanol fatty acid esters, where fatty acids contain 2 to 3 carbon atoms, are useful for reducing anoxia or stimulating heart response. Levin does not at all relate to or teach the utilization of policosanol fatty acid esters with 2 to 3 carbon atoms to treat hypercholesterolemia,

and is therefore believed not to be combinable with the other references, since it does not address the objective of using policosanols fatty acid esters, particularly those with a long chain of carbon atoms, for the purpose of treating *hypercholesterolemia*.

Granja (U.S. Patent No. 5,663,156) discloses that policosanols such as tetracosanol, hexacosanol, heptacosanol, and traicontanol are useful in compositions and methods for treating hypercholesterolemia and atherosclerosis. However, Granja teaches away from the use of fatty acid esters of policosanols for the treatment of hypercholesterolemia, because Granja et al. teaches hydrolyzing the esters, discarding the fatty acid residue, and using the free policanol mixture. Granja does not suggest the use of the waxes (policanol esters with long chain fatty acids) instead of the free policosanols for the use as cholesterol-lowering agents. Thus, Granja et al. is inapplicable prior art in that it teaches away the use of fatty acids together with policosanols by specifically claiming the discarding of fatty acid moiety of waxes.

Hasegawa (Claim Abst. 100:208354) teaches that compositions containing linoleic acids are useful for treating hypercholesterolemia. However, there is no basis to conclude that a policanol fatty acid ester will also yield a useful result in treating hypercholesterolemia. In fact, there is no basis to conclude that the above combination will yield a *synergistic* or *superior* effect compared to when they are used individually. There is no routine belief that where drug A and drug B are separately and individually useful in treating a certain condition, that the combination of these two will necessarily yield superior results. On the contrary, in view of Bundgaard, the assumption would be that no synergy would result.

The Bundgaard reference teaches that esters of active drug substances are hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate the active drug substance.

Bungaard teaches away the combination (policosanol fatty acid ester) because it teaches that the ester compound will be split within the body into single ester compounds, letting each moiety act independently.

For a rejection to be proper, the claimed invention as a whole of the rejected claim must have been obvious under §103. Although it is common to find features in the prior art, it is not isolated features but the subject matter as a whole that must be evaluated under 35 U.S.C. § 103. There are significant differences between the claimed invention and the prior art references that must be considered.

All of the prior art quoted by the Examiner lack significant features and do not contain suggestions to be combined with one another in a manner that justifies a conclusion of obviousness. Levin et al. discloses the use of policosanol fatty acid esters specifically with short chain carbon atoms to treat anoxia or heart response problems – in no way does it reveal the use of policosanol fatty acid esters to treat hypercholesterolemia, particularly where the fatty acid are of long chain carbon atoms. Granja et al. teaches simply the use of policosanols, while Hasegawa teaches simply the use of linoleic acids for treating hypercholesterolemia – nowhere do either reveal or imply that *the combination* of the two compounds would improve treatment of hypercholesterolemia. In fact, Granja et al. actually teaches away the use of fatty acid esters of policosanol. Finally Bundgaard teaches away the use of the combination of policosanols and linoleic acid by revealing that the synthesized ester compound would be split in vivo, leaving each component to act independently.

There is no discovery of synergy or superior functionality as is claimed by the Applicant's invention, whose conclusion was derived through multiple trials and significant research.

It is Applicant's belief that this application is in a condition for allowance. An action so indicating is respectfully requested. If the Examiner believes that discussion of this application would be beneficial, the undersigned may be contacted at the telephone number stated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David I. Roche". The signature is fluid and cursive, with the first name "David" and last name "Roche" clearly distinguishable.

David I. Roche
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